### **PCT**

# WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



# INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>5</sup> : A61K 9/12		(11) International Publication Number:	WO 95/02393 26 January 1995 (26.01.95)	
		(43) International Publication Date:		
(21) International Application Number: PCT/Us (22) International Filing Date: 15 July 1994	S94/0784 (15.07.9	HU, JP, KP, KR, NO, NZ, FL	, RO, RU, SE, SE, OA, VIV , DE, DK, ES, FR, GB, GR	
(30) Priority Data: 08/092,556 16 July 1993 (16.07.93)	τ	Published With international search repo	rt.	
<ul> <li>(71)(72) Applicant and Inventor: SIMMONS, Paul, L 6250 Kipps Colony Court #203, Gulfport, FL 33</li> <li>(74) Agent: FISHER, Arthur, W., III; Suite 316, 5553 W Avenue, Tampa, FL 33634 (US).</li> </ul>	707 (03	<i>,</i>		

# (54) Title: NON-TOXIC HYPOCOMPATIBLE BIODEGRADABLE GERMICIDE

#### (57) Abstract

A non-toxic hypocompatible biodegradable germicide effective against a wide range of pathogenic organisms comprising a composition including a monohydric alcohol from the group consisting of isopropyl, methyl, ethyl, n-propyl, n-butyl, tert-butyl or allyl or mixtures thereof and a polyhydric alcohol from the group consisting of propyleneglycol; 1,3 propanediol; 1,2 butanediol, PEG 400; glycerol or 1,4 butanediol or mixtures thereof in proportion by weight such that the polyhydric alcohol reduces the surface glaze formed by the monohydric alcohol and surface tension formed by water or water-based body fluids enabling the disinfectant/antiseptic to kill the pathogenic organisms and act equally effective on a patient or inanimate surface without deleterious effect to either.

### FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
ΑU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	TE.	Ireland	NZ	New Zealand
BJ	Beain	π	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic	SD	Sudan
CG	Congo		of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Scocgal
CN	China	LK	Sri Lanka	TD	Chad
cs	Czechoslovakia	LÜ	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	177	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gebon		-		

WO 95/02393

## **Description**

# Non-Toxic Hypocompatible Biodegradeable Germicide Copending Application(s)

This application is a continuation application of pending application Serial Number 846,249 filed February 24,1992; that is a continuation-in-part application of application Serial Number 642,709, filed January 17, 1991 and issued as US 5,145,663 on September 8, 1992; that is a continuation application Serial Number 304,312 filed January 31, 1989, now abandoned

## 10 <u>Technical Field</u>

5

15

20

25

A non-toxic hypocompatible biodegradable germicide effective against a wide range of pathogenic organisms.

### Background Art

Modern health care facilities are confronted with complex medical problems, whether in a practitioner's office, clinic or large hospital. Such facilities must care for persons with life-threatening diseases while protecting other patients in the same facility from becoming infected. Thus, controlling viral and microbial contamination is a critically important task facing health care facilities today. In the past, the health care industry believed that sanitation and disinfection applied primarily only to emergency rooms and

every area or the modern treatment facility—this awareness has been heightened by the rapid increases in the spread of deadly communicable

10

15

20

25

30

diseases such as the AIDS virus (HIV), hepatitis and tuberculosis, which The need for such protective means applies equally to contaminated surfaces not only to health care facilities but to such environs as public restrooms. telephones, tables and other surfaces contacted by the public as well as for topical application directly on a patient's skin. Various spray germicides for sanitizing such surfaces is typified by in U.S. 3,445,564. US 3,445,1564 is directed to a method, compositions and articles for sanitizing public or communal facilities prior to individual use. The method consists of applying a thin layer of a rapidly drying liquid germicidal composition to a surface such as a toilet seat. The rapidly drying germicidal compositions consist essentially of a lower aliphatic alcohol and at least about 5 percent of a volatizing agent therefor, such as acetone. Isopropyl alcohol has excellent germicidal activity and is sufficiently volatile to give a satisfactory drying rate when blended with suitable proportions of a volatilizing agent. Inasmuch as the lower aliphatic alcohols are not sufficiently volatile to afford usefully short drying times for practical purposes in the method and articles of the Kirschner invention it was necessary to include a volatilizing agent in the germicidal composition. The proportion of volatizing agent to lower aliphatic alcohol in the rapidly drying germicidal compositions employed in the invention may vary widely depending upon a number of factors, which include among others, the volatility of the alcohol employed, the volatility of the volatilizing agent, the desired drying rate of the germicidal composition. the amount of germicidal agent applied to the surface to be treated and the method of application of the germicide, not to mention the prevailing conditions of temperature and although the isopropyl alcohol-acetone composition of U.S. 3,445,564 has germicidal activity against bacteria, fungi and other lower organisms, additional antibacterial, antifungal or other active ingredients may be incorporated to enhance the overall germicidal effectiveness. Suitable germicidal additives include the-well known antibacterial quaternary ammonium compound. In essence, US 3,445,564 teaches the use of isopropyl alcohol to kill a limited number of germs on a

PCT/US94/07805 WO 95/02393

5

10

15

20

25

30

3

dry toilet seat with the addition of acetone to volatize an already highly volatile chemical to rapidly dry the toilet seat for use within 30 seconds. The use of a dye in a bactericidal solution as disclosed in US 2,449,274 is employed to provide a visual indication of the effectiveness of such sprays. US 4,678,658 shows an aerosol spray for use in disinfecting a surface for personal use such as a public restroom facility or telephone. The composition and delivery of the compositions provides for the placement of a spray of disinfectant which includes a dye that disappears as the spray effects the germicidal activity of the disinfectant. The composition is also rapidly drying, so that the dye disappears as well as the disinfecting composition leaving the surface dry. However, the spray is corrosive and environmentally unsafe. US 3,821,413 discloses a formulation of materials which permits an effective, uniform rate of evaporation of glycols from an air circulator device to reduce airborne bacteria in the surrounding atmosphere. It was observed that the relative amounts and identities of the components of the invention are critical to the attainment of the desired continuous evaporation of glycols over a prolonged period of time. The composition of US 3,821,413 is a single phase liquid composition especially adapted for volatilization at a substantially uniform rate from the air circulator device. Generally speaking, the composition includes three essential components (1) a glycol, (2) an organic polar coupling compound for maintaining the homogeneity prevents the glycol from separating from the mixture during evaporation of the mixture into the atmosphere and (3) an organic, relatively non-polar compound for forming hydrophobic micelles with the glycol molecules in the resulting mixture for reducing the affinity of the glycol to atmospheric moisture and thereby increasing the rate at which the glycol may be evaporated into the atmosphere. The composition contains the was alds. If desired other suitable germicides or antiseptic agents

composition does not fail below a percent by weight of the rotal mixture. Such germicides include quaternary ammonium compounds, phenols,

1.4.4.00

bisphenols, salicylanilides, carbanilides, formaldehyde and chloride. The required glycol evaporation rate for attaining the desired air sanitizing performance depends on the satisfactory stability and uniform nature of the liquid composition during evaporation from the mixture. Accordingly, the compositions of the invention include from about 2 percent to about 40 percent by weight of an organic polar coupling compound for maintaining the homogeneity of the mixture to prevent the glycol from separating from the mixture during the evaporation process. The affinity of glycols to attract atmospheric moisture significantly reduces their volatility and impairs their evaporation rate. Accordingly, the compositions of the invention include from about 5 percent to about 80 percent by weight of an organic, relatively non-polar compound for forming hydrophobic micelles surrounding the glycol molecules in the mixture for reducing the affinity of the glycol to atmospheric moisture and thereby increase the rate of evaporation of the glycol. Without this micelle formation, it was found that the glycol or mixture of glycols in the mixture cannot evaporate appreciably in an air circulator device containing a wick immersed in the liquid composition. US 3,806,593 is directed to an acne treatment medication applied to the skin for preventing the formation of acne or decreasing already established acne. An important factor for the occurrence of acne is the presence of bacteria in the sebaceous glands in the skin. It is known that the bacteria in the sebaceous glands form esterases which hydrolyze the sebum fats to alcohols and free fatty acids. The medicinal acne-preventing or acne-diminishing composition of US 3,806,593 is based on the bacterial esterase activity in the sebaceous glands which together with the water already present in the skin can hydrolyze an ester having a good penetration capacity into the sebaceous glands to form one and preferably two antibacterially active components, viz. an acid and an alcohol, which are harmless to the skin. The active compound in the composition is one or more esters chosen from the group consisting of ethyl lactate, isopropyl lactate and/or glycerol mono or dilactate. The esters hydrolyze in the sebaceous glands due to the

5

10

15

20

25

10

15

20

25

esterases present in the glands to form the corresponding acids and alcohols. Lactic acid and the lower alcohols and also glycerol to a certain extent exert a good antibacterial activity when formed in situ in the sebaceous glands,. The esters are lipophilic and can thus penetrate into the said glands. Even if a beneficial action can be achieved by application of the ester or esters per se it has been found to be suitable to apply the ester in the form of a solution in ethyl alcohol or isopropyl alcohol. The alcohol prevents hydrolysis of the ester already in the composition. The alcohol moves the hydrolysis equilibrium towards ester formation. The alcohol can also facilitate the penetration of the ester into the skin. As is well-known alcohol in high concentrations may cause a drying-out of the skin. To counteract this effect, the composition may include a moisture-retaining agent such as a lower, suitably water-free polyol, viz. propylene glycol or alycerol. The content of propylene glycol or glycerol in the composition according to the invention may be up to 25 percent, suitably not more than 10 percent by weight and preferably 1-5 percent. High levels of polyol tend to make the composition smeary upon application on the skin and should thus be avoided. The preferred composition according to the invention consists of about 15 percent by weight of ethyl lactate, about 2 percent by weight of propylene glycol, the remainder being ethyl alcohol. In summary, US 3,806,593 relates to acne medication comprising esters that hydrolize in the sebaceous glands in combination with an alcohol to prevent hydrolysis of the esters as well facilitate the penetration of the ester into the skin, and propylene glycol or glycerol to prevent drying of the skin. The preferred ratio of the constituents is 15 percent to 83 percent to 2 percent respectively. US 4,664,909 discloses a stable, fast drying pituitous powder deodorant suspension in an alcohol media containing a minimal amount of water and a critical amount of the essential hydroxyethyl cellulose as the suspending

normal solubility limit by polyhydric alcohol. More specifically US 4,664,909

relates to stable pituitous suspensions of particulate material, preferably about 1-20 percent, uniformly suspended in alcohol/aqueous media containing a high alcohol content and a lower water content. The alcohol media may be a lower monohydric alcohol selected from the group consisting of methanol, ethanol, isopropanol and mixtures thereof. The use of polyhydric alcohols such as propylene glycol, butylene glycol and polyols thereof, and glycerin decreases the critical water level required in the hydroxyethyl cellulose-containing alcohol media. It has been unexpectedly found that powders can be suspended in alcoholic/aqueous media containing a high alcohol content and a lower water content by using the water soluble polymer hydroxyethyl cellulose at critical levels above its ethanol solubility range which may be broadened by specified polyhydric alcohols. This polymer is unique in its property to form stable suspensions. Specifically, polyhydric alcohols can be partially substituted for the monohydric alcohol, not to exceed the monohydric alcohol content. The monohydric alcohol content, such as ethanol, must exceed the upper solubility level for the water soluble polymer hydroxyethyl cellulose in ethanol or other lower alkanol. The reported upper solubility level of this water soluble polymer in ethanol is 70 percent. Below this level and within normal soluble use ranges, a uniformly viscous liquid is obtained which pours evenly. Although, it appears aesthetically desirable, it will not support suspended powder and segregation occurs. However, at ethanol concentrations above its solubility range, the polymer becomes less soluble and forms the desired pititious type liquid. If ethanol is further increased resulting in very low water levels the polymer will precipitate out and its suspending properties are again lost. Accordingly, a 70:30 ratio of ethanolwater is optimum. However, it was found that this problem can be eliminated by the sufficient addition of a polyhydric alcohol such as glycerin, propylene glycol, butylene glycol and polyglycols thereto. Accordingly, it has been found that the monohydric alcohol constitutes about 55-85 percent; and the water content may be as low as 5 percent if at least 10 percent polyhydric

5

10

15

20

25

10

15

20

25

alcohol is also present in the suspension. The combined water and polyhydric alcohol content is at least 15 percent and may be up to about 25 percent. Thus, it is apparent that the proportions of monohydric alcohol, water and polyhydric alcohol are interdependent. In summary, US 4,664,909 teaches a fast-dryingdeodorant comprising a critical amount of hydroxyethylcellose as the deodorant to encapsulate or isolate bacteria to prevent growth of the bacteria, suspended in a solution of monohydric alcohol to provide the fast drying characteristics and polyhydric alcohol to improve the overall soluability of the solution to allow the use of increased levels of monohydric alcohol. The relative proportions of themonohydric alcohol, water and polyhydric alcohol are driven or determined by the desired solubility and therefore are interdependent. U.S. 3,966,902 disclosed various polymer complex carriers such as propylene glycol for use with an active ingredient such as a disinfectant or fragrance. U.S. 4,690,779 refers to the use of propylene glycol in combination with alcohol and fragrances. This composition is both toxic and non-biodegradable. U.S. 4,209,500 teaches a composition suitable for use in aerosol sprays including an anhydrous alcohol and fragrance or perfume. This composition is corrosive, non-biodegradable and non-evaporative. Additional examples of the prior art are found in U.S. 580,213, U.S. 4,282,179, U.S. 4,265,899, U.S. 4,283,421, U.S. 4,364,515, U.S. 4,550,105, U.S. 4,105,431, U.S. 4,243,403, U.S. 4,278,206, U.S. 4,322,475, U.S. 4,436,732, U.S. 4,597,887, U.S. 4,252,694, U.S. 4,279,762, U.S. 4,325,201, U.S. 4,540,505 and U.S. 4.675,397. Examination of the prior art reveals that most existing disinfectants are either toxic or non-biodegradable or both. Toxic chemicals that are not biodegradable contaminate the environment, the soil and the water supply. Recent federal, state and local regulations are designed to reduce or eliminate such environmental contamination resulting from the use

rigalth facilities are required to notify employees that toxic chemicals are use and inform them of the possible hazards that result or could result as a

WO 95/02393 PCT/US94/07805

8

consequence of misuse or spills. Such notices must also be given to the community at Other laws and regulations require users to document the use of toxic chemicals and require that the excess, waste and residue be collected and properly stored. These materialsmust be collected by licensed and approved toxic waste companies, taken to authorized disposal sites and legally destroyed. The cost of disposing of such toxic material is often more expensive than the initial purchase price. Simply stated, the prior art fails to teach or suggest an effective non-toxic biodegradable surface active disinfectant/antiseptic for application on contaminated surfaces or for safe use on a patient's skin. Disinfectants today should be non-toxic as well as biodegradable, capable of killing or inactivating pathogenic organisms. Further, such disinfectants should be chemically compatible with the numerous different surfaces found in modern healthcare facilities. As described more fully hereinafter the instant invention is directed to an environmentally safe germicide capable of killing anaerobic and aerobic bacteria, viruses including the HIV virus, mildew, mold and fungus. The principal active anti-microbial, anti-viral ingredients of the instant invention are selected from a group of monohydric alcohols and polyhydric alcohols. In the past such alcohols have had limited use outside the laboratory due to various undesirable characteristics of alcohol. For example, it has been universally accepted that alcohol has very limited application as a widely used disinfectant because alcohol is unable to penetrate protein rich material, evaporates quickly, has limited stability and shelf life, has a pungent odor, tends to form a glaze on hard surfaces possibly hiding or covering visible contamination and dries the skin. The instant invention has involved an extensive development program involving the unexpected formulation of certain chemicals to reduce or inhibit those undesirable features of alcohol and to make alcohol safe and effective for use outside the laboratory.

BNG(F, K)E/ W / 9502393A1 I S

5

10

15

20

10

15

20

25

della e

### **Disclosure Of The Invention**

The present invention relates to a non-toxic hypocompatible biodegradable germicide for topical application on a patient's skin or to inanimate surfaces to kill a wide range of pathogenic organisms. The biodegradable germicide comprises a composition including a monohydric alcohol from the group consisting of isopropyl, methyl, ethyl, n-propyl, nbutyl, tert-butyl alcohol or allyl alcohol and/or mixtures thereof and a polyhydric alcohol from the group consisting of propylene glycol; 1,3 propanediol; 1,2 butanediol, PEG 400; glycerol or 1,4 butanediol and/or mixtures thereof in proportion by weight such that the polyhydric alcohol reduces the surface glaze formed by the monohydric alcohol and surface tension formed by water or water-based body fluids enabling the germicide to kill the pathogenic organisms and act equally effective on a patient or inanimate surface without deleterious effect to either. The monohydric alcohol provides the primary disinfecting or killing effect on the pathogenic organisms; while, the polyhydric alcohol lowers the flash point of the composition and soothes the skin. The polyhydric alcohol also slows the rate of evaporation, reduces or eliminates the intersurface glazing effect of monohydric alcohol and homogenizes the interactive ingredients. The relative proportions by weight of interactiveing redients chemically reduces the tensile strength of the surface liquids on the patient's skin or other surface permitting the germicidal effect to act directly on the pathogenic organisms. The non-toxic hypocompatible biodegradable germicide in liquid form may be dispensed in various delivery systems including spray, foam, pour and squirt for a aerosol or non-aerosol product. Alternate systems may include a towelette or an absorbent wipe containing the product in an airtight enveloping material such as sealed foil or other wrapping material could be used for a single application. The invention accordingly comprises the

which will be exemplified in the construction bereinafter set forth. and the scope of the invention will be indicated in the claims.

### Best Mode For Carrying Out The Invention

Numerous germicidal compositions and delivery devices have been developed to kill various pathogenic organisms. The wide range of application or use is limited by the chemical and biological effect of such compositions on the various surfaces, delivery means and patients exposed to such germicidal compositions. The present invention relates to a nontoxic hypocompatible biodegradable germicide for topical application on a patient's skin or on hard surfaces' such as restrooms or tables effective against a wide range of target pathogenic organisms such as Bacteria including staphylococcus aureus, pseudomonas aeruginosa and salmonella coleraesuis and Viruses including HIV-I, HIV-II, tuberculosis, polio and herpes simplex type 2, as well as fungi (trichophyton mentagrophytus), mold and mildew through alternate delivery means. The germicide comprises a non-toxic hypocompatible biodegradable composition of selected monohydric alcohols selected polyhydric alcohols and water combined in relative proportions by weight such that the composition may be used topically to cleanse a patient's skin or to disinfect various public surfaces through direct application with equal effectiveness without deleterious effect to either. The monohydric alcohol is selected from the group onsisting of isopropyl, methyl, ethyl, n-propyl, n-butyl, ert-butyl or allyl or mixtures thereof and the polyhydric Icohol is selected from the group consisting of propylene lycol; 1,3 propanediol; 1,2 butanediol, PEG 400; glycerol or .4 butanediol or mixtures thereof.

As used herein, the term non-toxic refers to the equirements of the LD 50 Oral Toxicity Test; that is, on-toxic, non-poison, to rate at 50 times the lethal dose. used herein, the term biodegradable refers to ecomposition in the presence of 25 percent organic material ithin 90 days at 69 degrees F (Standard Temperature) with oisture content of 100 parts per million. As used herein, the term challenge refers to a test colony or specimens of 106 specified pathogenic organisms. As used herein, the term azeotropic means a constant boiling liquid admixture of two or more substances, whose

PNSDOXIE - WC - 1502393A C F S

5

10

15

20

25

10

15

20

25

30

admixture behaves as a single substance, in that the vapor, produced by partial evaporation or distillation of the liquid has the same composition as the liquid, i.e., the admixture distills without substantial composition change. Constant boiling compositions, which are characterized as azeotropic, exhibit either a maximum or minimum boiling point, as compared with that of the nonazeotropic mixtures of the same substances. As used herein, the term organic means the presence of less than about 10 percent by weight of free water within a solution. As used herein, the term aqueous means the presence of more than about 10 percent by weight of free water within a solution. The specific monohydric alcohols and polyhydric alcohols and relative ratios thereof optimize the particular characteristics of solubility, specific gravity, conductivity, pH, flash point, boiling point and evaporation essential to the effective use of the instant germicide against the bioburden as defined herein on pathogens as described herein with a nontoxic effect as defined herein on patients, and with a hypocompatible effect as defined herein on the surfaces described herein. Specifically, the presence of the polyhydric alcohol raises the boiling point of the germicide slowing the rate of evaporation of the germicide. As a solvent, the polyhydric alcohol prevents the tendency of monohydric alcohol to form a glaze on the target surface that masks the pathogenic organisms and breaks the barrier formed by surface tension of water and water-based body fluids enabling the germicide to act on the pathogens more rapidly. In addition, the polyhydric alcohol serves as an emulsifier to assure that the composition remains homogenized during storage and use, further, the polyhydric alcohol reduces the harmful effects of monohydric alcohol if swallowed or sprayed into the eyes or on mucus membranes as well as soothing the skin upon contact. Since the polyhydric alcohol reduces toxicity to human cells the need to to the permiside has been eliminated. Polyhydric alcohol also acts as a

used, tests indicate that the polyhydric alcohol increases the everal:

effectiveness of the germicide against most viruses, mold and mildew. Since

refra to the state of the state

WO 95/02393 PCT/US94/07805

12

the germicide was developed for use on a wide variety of surfaces and dispensed from a number of dispensing modes or means of dispersant materials the measure of chemical resistance is important to permit broad use and application. To be effective, the germicide must be hypocompatable with CPVC, Epoxy, Polypropylene, PVC, Cyolac (ABS), Phenolic, Nylon, Noryl, Delrin (Acetal), Ryton to 200%F, Kynar, Teflon, Stainless Steel 316, Stainless Steel 304, Carpenter 20, Stainless steel (440), Titanium, Cast Bronze, Cast Iron, Aluminum, Hastelloy C, Carbon/ceramic, Ceramagnet A, Viton, Buna N., Neoprene, Nitrile, Natural rubber, Hypalon, EPDM, Kel-F. Tygon, Silicone, Ceramic and Carbon/graphite. As used herein, the term hypocompatible shall mean no material degradation efforts associated with surfaces to include, for example, discoloration, corrosion, cracking, crazing and embrittlement. Comparative results of the germicide with the individual constituents have demonstrated that the combination of interactive ingredients provides a germicide effective against an expansive range of materials found in a wide variety environments through various delivery means such as aerosol, pump, spray or swab without degradation of the materials. In order to accomplish the design criteria of a non-toxic. hypocompatible, biodegradable germicide effective against the wide range of pathogenic organisms described herein, the composition should have a pH of between about 7 and 5, virtually evaporate before about 6 and 20 minutes to have an effective kill time of about 8 to 12 minutes and prevent surface residue, a specific gravity of about .85, viscosity below 4 and relatively no conductivity. The effective proportional relationship of the ingredients by weight for the monohydric alcohol as described herein is between about 65 percent to about 75 percent, for the polyhydric alcohol as described herein is between about 4 percent and about 16 percent and for the water is between about 9 percent to about 18 percent.

The preferred proportional relationship of the active ingredients by weight is about 70 percent for the monohydric alcohol and between about 8 percent to about 12 percent for the polyhydric alcohol and between about 14

5

10

15

20

25

10

15

20

25

percent to about 18 percent water. The preferable amount of polyhydric alcohol is 6 to 14 percent by weight. Less than 4 percent of polyhydric alcohol by weight does not provide adequate kill and exhibits an excessive alkaline pH; while, more than 16 percent of polyhydric alcohol by weight leaves a residue to attract and harbor pathogens. However, the composition is most effective with about 10 percent polyhydric alcohol, about 70 percent monohydric alcohol, and about 16 percent water all by weight. The solution comprises a binary azeotropic composition formed by the chemical bonding between the monohydric alcohol and water in correct proportion to lengthen shelf life, reduce evaporation and rust, and enhance efficacy. Specifically, because the azeotrope is stable, the composition will maintain the efficacy for long periods of time. The azeotropic bond between the monohydric alcohol and water causes the combination to evaporate together thus maintaining substantially the same relative concentration of monohydric alcohol and water to retain sufficient potency to kill the target organisms. Moreover, because the water is bonded to the monohydric alcohol, the ability to oxidize metal (rust) is greatly reduced. Thus, after registering significant amounts of evaporation in laboratory tests, presumed loss of efficacy would be expected. Because of the azeotrope however, even after a 33 percent weight loss, the concentration of monohydric alcohol was still at 66 percent. Therefore, most of the evaporation was from the free water plus some of the azeotropic monohydric alcohol. Regardless of extended shelf life, exposure to air in an ultrasound, or carelessness with regard to keeping containers tightly sealed, the required concentration of monohydric alcohol essential to achieve accepted and required testing protocols will be maintained. In the total concentrations used in the solution about 70 percent monohydric alcohol requires about 10 percent water to be greatropic. To provide the ability to kill the hydrophobic organisms.

me azeotropic equilibrium may be added without degradation of the monohydric alcohol/water azeotrope. The addition of between about 2

10

15

20

percent and 4 percent by weight of a surfactant such as sodium dodecyl sulfate, octyl phenoxy polyethoxyethanol, triethanol amine lauryl sulfate and mixtures thereof permits the use of the composition as a surface disinfectant capable of dislodging and absorbing as much as twenty five percent organic matter from an inanimate surface. The addition of between about 1 percent and 2 percent by weight of a sporicide such as an N(hydroxymethyl) acetamide derivative permits the use of the composition as a sterilant capable of killing bacillus subtilis and clostridium sporogenes. By adding a resin such as Carbonol 940 brand carboxy polymethylene by BF Goodrich from about 0.1 percent to 2.0 percent by weight to increase viscosity, the composition may be used as a commercial or industrial disinfecting lubricant. It will thus be seen that the objects set forth above, among those made apparent from the preceding description are efficiently attained and since certain changes may be made in the above construction without departing from the scope of the invention, it is intended that all matter contained in the above description shall be interpreted as illustrative and not in a limiting sense. It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween. Now that the invention has been described.

10

15

### <u>Claims</u>

- A non-toxic hypocompatible biodegradable germicide effective against 1. a wide range of pathogenic organisms including bacteria including staphylococcus aureus, pseudomonas aeruginosa and salmonella choleraesuis and viruses including HIV-I, HIV-II, tuberculosis, polio and herpes simplex type 2, fungi (trichophyton mentagrophytes), mold and mildew, said surface disinfectant comprising at least 65 percent by weight of a monohydric alcohol, a polyhydric alcohol and less than 20 percent by weight of water mixed homogeneously and performing interactively in a proportion by weight such that said polyhydric alcohol reduces the surface glaze formed on the pathogenic organisms and the surface to be disinfected by the particular monohydric alcohol and surface tension of water or waterbased body fluids containing the pathogenic organisms found on the surface to be disinfected enabling said germicide to rapidly contact the pathogenic organisms to kill the pathogenic organisms before evaporation of said monohydric alcohol equally effective on a patient orinanimate surface without deleterious effect to either.
- 2. The non-toxic hypocompatible biodegradable germicide of Claim 1
  20 effective against a challenge of the pathogenic organisms including bacteria including staphylococcus aureus, pseudomonas aeruginosa and salmonella coleraesuis and viruses including HIV-I, HIV-II, tuberculosis, polio and herpes simplex type 2, fungi (trichophyton mentagrophytus), mold and mildew.

25

3. The non-toxic hypocompatible biodegradable germicide of Claim 1 wherein said monohydric alcohol is selected from the group consisting of

WO 95/02393 PCT/US94/07805

16

4. The non-toxic hypocompatible biodegradable germicide of Claim 1 wherein said polyhydric alcohol is selected from the group consisting of propylene glycol; 1,3 propanediol; 1,2 butanediol, polyethylene glycol; glycerol and 1,4 butanediol or mixtures thereof.

5

- 5. The non-toxic hypocompatible biodegradable germicide of Claim 1 including about 70 percent of said monohydric alcohol by weight.
- 6. The non-toxic hypocompatible biodegradable germicide of Claim 5
   10 including about 8 percent to about 12 percent of said polyhydric alcohol by weight.
  - 7. The non-toxic hypocompatible biodegradable germicide of Claim 6 including about 10 percent of said polyhydric alcohol by weight.

- 8. The non-toxic hypocompatible biodegradable germicide of Claim 7 including about 16 percent of water by weight.
- A non-toxic hypocompatible biodegradable azeotropic germicide 9. 20 effective against a challenge of pathogenic organisms including bacteria including staphylococcusaureus, pseudomonas aeruginosa and salmonella choleraesuis and viruses including HIV-I, HIV-II, tuberculosis, polio and herpes simplex type 2, fungi (trichophyton mentagrophytes), mold and mildew, comprising a homogenous composition of interactive constituents, including about 70 percent of a monohydric alcohol and including about 10 25 percent of a polyhydric alcohol by weight such that said polyhydric alcohol reduces the surface glaze formed by said monohydric alcohol and surface tension formed by water or water-based body fluids enabling said azeotropic germicide to rapidly organisms before evaporation of said monohydric 30 alcohol equally effective on a patient or inanimate surface without deleterious effect to either.

PCT/US94/07805

25

- The non-toxic hypocompatible biodegradable azeotropic germicide of Claim 9 containing less than about 20 percent of water by weight.
- A non-toxic hypocompatible biodegradable germicide effective against 11. a challenge of 10 6 of pathogenic organisms including bacteria including 5 staphylococcus aureus, pseudomonas aeruginosa and salmonella choleraesuis and viruses including HIV-I, HIV-II, tuberculosis, polio and herpes simplex type 2, fungi (trichophyton mentagrophytes), mold and mildew, said surface disinfectant being a homogenous composition comprising of at least 65 percent by weight of a monohydric alcohol, a 10 polyhydric alcohol and water with the proviso that said monohydric alcohol and said polyhydric alcohol are selected and used in amounts such that said monohydric and said polyhydric alcohol perform interactively in a proportion by weight such that the particular polyhydric alcohol reduces the surface glaze formed on the pathogenic organisms by the particular monohydric 15 alcohol and surface tension of water orwater-based body fluids containing the pathogenic organisms on the surface to be disinfected enabling said germicide to rapidly contact the pathogenic organisms to kill the pathogenic organisms before evaporation of said monohydric alcohol equally effective on a patient or inanimate surface without deleterious effect on either. 20
  - 12. A non-toxic hypocompatible biodegradable germicide effective against various pathogenic organisms including bacteria including staphylococcus aureus, pseudomonas aeruginosa and salmonella choleraesuis and viruses including HIV-I, HIV-II, tuberculosis, polio and herpes simplex type, fungi (trichophyton mentagrophytes), mold and mildew, said surface disinfectant consisting essentially of about 65 to about 75 percent by weight of a

polynydric alcohol reduces the surface glaze formed on the pathogenic organisms on the surface to be disinfected by the particular monohydric

PCT/US94/07805

alcohol and surface tension of water or water-based body fluids containing the pathogenic organisms found on the surface to be disinfected enabling said germicide to rapidly contact the pathogenic organisms to kill the pathogenic organisms before evaporation of said monohydric alcohol equally effective on a patient or inanimate surface without deleterious effect to either.

13. The non-toxic hypocompatible biodegradable germicide of Claim 12 including about 70 percent of said monohydric alcohol by weight.

10

5

- 14. The non-toxic hypocompatible biodegradable germicide of Claim 13 including about 8 percent to about 12 percent of said polyhydric alcohol by weight.
- 15. The non-toxic hypocompatible biodegradable germicide of Claim 14 including about 10 percent of said polyhydric alcohol by weight.
  - 16. The non-toxic hypocompatible biodegradable germicide of Claim 15 including about 16 percent of water byweight.

20

17. A non-toxic hypocompatible biodegradable germicide effective against a challenge of pathogenic organisms including bacteria including staphylococcus aureus, pseudomonas aeruginosa and salmonella choleraesuis and viruses including HIV-I, HIV-II, tuberculosis, polio and herpes simplex type 2, fungi (trichophyton mentagrophytes), mold and mildew, comsisting of a homogenous composition of interactive constituents, including about 70 percent of a monohydric alcohol by weight and including about 10 percent of a polyhydric alcohol by weight such that said polyhydric alcohol reduces the surface glaze formed by said monohydric alcohol and
30 surface tension formed by water or water-based body fluids enabling said germicide to rapidly contact the pathogenic organisms to kill the pathogenic

organisms before evaporation of said monohydric alcohol equally effective on a patient or inanimate surface without deleterious effect to either.

- 18. The non-toxic hypocompatible biodegradable germicide of Claim 17wherein said composition is azeotropic.
  - 19. The non-toxic hypocompatible biodegradable azeotropic germicide of Claim 18 containing less than about 20 percent of water by weight.
- A non-toxic hypocompatible biodegradable germicide effective against 10 20 a challenge of 10 6 of pathogenic organisms including bacteria including staphylococcus aureus, pseudomonas aeruginosa and salmonella choleraesuis and viruses including HIV-I, HIV-II, tuberculosis, polio andherpes simplex type 2, fungi (trichophyton mentagrophytes), mold and mildew, said germicide being a homogenous composition consisting of at 15 least 65 percent by weight of a monohydric alcohol, a polyhydric alcohol and water with the proviso that said monohydric alcohol and said polyhydric alcohol are selected and used in amounts such that said monohydric and said polyhydric alcohol perform interactively in a proportion by weight such that the particular polyhydric alcohol reduces the surface glaze formed on 20 the pathogenic organisms by the particular monohydric alcohol and surface tension of water or water-based body fluids containing the pathogenic organisms on the surface to be disinfected enabling said germicide to rapidly contact the pathogenic organisms, to kill the pathogenic organisms before evaporation of said monohydric alcohol equally effective on a patient or 25 inanimate surface without deleterious effect to either.

### INTERNATIONAL SEARCH REPORT

I national application No. PCT/US94/07805

A. CLASSIFICATION OF SUBJECT MATTER IPC(5): A61K 9/12 US CL: 424/47 According to International Patent Classification (IPC) or to both	national classification and IPC						
B. FIELDS SEARCHED							
Minimum documentation searched (classification system followed by classification symbols)							
U.S. : 424/76.8, 514/975, 422/28							
Documentation searched other than minimum documentation to the	e extent that such documents are included in t	the fields searched					
Electronic data base consulted during the international search (na	ame of data base and, where practicable, see	arch terms used)					
C. DOCUMENTS CONSIDERED TO BE RELEVANT							
Category* Citation of document, with indication, where ap	opropriate, of the relevant passages	Relevant to claim No.					
Y US, A, 4,511,486 (SHAH) 16 A lines 66-68, column 2, lines 22-3 column 3, lines 5-7, 35, column 2	5, column 2, lines 52-54,	-20					
Further documents are listed in the continuation of Box C	. See patent family annex.						
Special categories of cited documents:	"T" inter document published after the internsti- date and not in conflict with the application						
"A" document defining the general state of the art which is not considered to be part of particular relevance	principle or theory underlying the invention						
*E* earlier document published on or after the international filing date	"X" document of particular relevance; the clair considered novel or cannot be considered to						
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other	when the document is taken alone						
special resson (as specified)	"Y" document of particular relevance; the clair considered to involve an inventive step						
*O* document referring to an oral disclosure, use, exhibition or other means	combined with one or more other such doc being obvious to a person skilled in the art						
*P" document published prior to the international filing date but later than the priority date claimed	*&* document member of the same patent famil	ly					
Date of the actual completion of the international search  12 SEPTEMBER 1994	Date of mailing of the international search 27 SEP 1994	report					
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer Included EDWARD J. WEBMAN	vd fol					
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2351						

Form PCT/ISA/210 (second sheet)(July 1992)\*